

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: <i>Jana Garvin, et al. v. Ethicon, Inc., et al.</i> Case No. 2:13-cv-19899	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN SUPPORT OF DEFENDANTS’ MOTION TO LIMIT
THE CASE-SPECIFIC TESTIMONY OF DANIEL ELLIOTT, M.D.**

Defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”) submit this brief in support of their Motion to Limit the Case-Specific Testimony of Daniel Elliott, M.D.

SUMMARY OF ARGUMENT

Plaintiffs have designated Dr. Elliott, a pelvic surgeon and urologist with experience installing and removing sling systems, as an expert in this case. *See* Ex. A, Elliott Case-Specific Expert Report. The vast majority of Dr. Elliott’s “case-specific” report in this matter is simply a verbatim copy of general opinions that he has previously given. With respect to these general opinions, Defendants adopt the Motion to Exclude Certain General Opinions of Daniel Elliott, M.D., filed in Wave 11.

For the reasons set forth below, the Court should exercise its gatekeeping role and preclude Dr. Elliott from testifying that the warnings provided to Ms. Garvin were inadequate. Such matters are inadmissible because Dr. Elliott is not qualified to offer them, and his opinions would be prejudicial, irrelevant, and a waste of time. Dr. Elliott’s opinions regarding certain

future conditions that Ms. Garvin might experience should also be excluded. Dr. Elliott engages in speculation and offers unreliable and unfairly prejudicial conclusions that do not fit the facts of this case. Furthermore, Dr. Elliott's warning opinions and opinions on future conditions should be excluded under Fed. R. Evid. 403, because they would only serve to unfairly prejudice Ethicon, and allowing this irrelevant testimony would be a waste of time.

ARGUMENT

Ethicon incorporates by reference the legal standard for Daubert motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014). Plaintiffs have designated Dr. Elliott as both a general and case-specific expert. The first thirty-four (34) pages of Dr. Elliott's case-specific report, however, have nothing to do with Ms. Garvin specifically. Instead, they concern his general opinions about the TVT-O device, the Instructions for Use and warnings, and prior studies of the device. *See* Ex. A, Elliott Case-Specific Report at 1-35. Because none of these opinions relate to Ms. Garvin specifically, Ethicon incorporates its Motion to Exclude the General Opinions of Dr. Elliott for Wave 11 and does not rebut those arguments separately herein. Ethicon respectfully requests that the Court exclude Dr. Elliott's testimony for the reasons expressed in the Wave 11 briefing, as well as the case-specific reasons set forth below.

I. The Court should exclude Dr. Elliott's warning opinions.

A. Lack of Expertise

Dr. Elliott is an Associate Professor of Urology at Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. Ex. A, Elliott Case-Specific Report at 1. Among other opinions, Dr. Elliott appears to assert that the IFU for TVT-O should have included additional warnings about alleged risks related to implantation, and that Ms. Garvin was unable to properly

consent to surgery due to the lack of this information. *Id.* at 45 (“1. Ms. Garvin was not able to make a fully informed medical decision regarding the implantation of the TVT-O polypropylene mesh because Ethicon failed to fully disclose the risks, complications (both early and late), and the consequences thereof, in Ethicon’s Instructions for Use.”)

For the reasons set forth in Ethicon’s Motion to Exclude the General Opinions of Dr. Elliott for Wave 11 regarding Dr. Elliott’s lack of qualifications to offer warning opinions, as well as for the case-specific reason set forth below, Ethicon respectfully requests that the Court exclude Dr. Elliott’s testimony regarding warnings.

B. Lack of Causation

Aside from Dr. Elliott’s lack of qualifications to offer warning opinions, Dr. Elliott’s warning opinions are irrelevant because Ms. Garvin’s implanting physician, Dr. Virginia Stokes, testified that different warnings would not have changed her decision to use the TVT-O, that she did not rely on the TVT-O IFU in making her treatment decision for Ms. Garvin, and that she was independently aware of potential adverse events of the TVT-O. *See* Ex. B, Stokes 6/6/19 Dep. Tr. 113:6-114:18; 117:12-119:11; 141:8-144:13; 146:8-147:25.

Kentucky recognizes the learned-intermediary doctrine, under which a device manufacturer discharges its duty to warn if the manufacturer adequately warns the prescribing physician; there is no duty to warn the patient directly. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 761 (Ky. 2004). “To plead a failure to warn claim in a prescription drug case, a plaintiff must allege facts for the Court to infer that (1) the manufacturer failed to provide his prescribing physician with adequate warnings about risks of which it knew or should have known and (2) the inadequate warnings proximately caused his injuries.” *Estate of DeMoss by & through DeMoss v. Eli Lilly & Co.*, 234 F. Supp. 3d 873, 880 (W.D. Ky. 2017). When evaluating the adequacy or

need for a warning, the expertise of the users of the product (the prescribing physician) must be considered, and a manufacturer may rely on the knowledge of a reasonable professional prescribing the product. *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 706-707 (E.D. Ky. 2003). Moreover, where there is no evidence that a physician or patient actually used the warning provided, they cannot be said to have relied on it. *Hardy v. Royce Labs., Inc.*, No. 2000 WL 33960115, at *4 (W.D. Ky. Jan. 3, 2000).

Here, Dr. Stokes testified that she did not use the IFU to consult with Ms. Garvin in advance of her surgery, and that all of the additional warnings Plaintiffs suggest should have been included in the IFU were known risks, of which Dr. Stokes was aware and would have conveyed to her patients. Ex. B, Stokes 6/6/19 Dep. Tr. 113:6-114:18; 117:12-119:11; 141:8-144:13; 146:8-147:2. Thus, the warnings outlined in Ms. Garvin's TVT-O IFU were adequate, and even if they were not (an assertion with which Ethicon disagrees), any lack of adequate warning cannot be deemed the proximate cause of Ms. Garvin's injuries. Under Kentucky law, Dr. Elliott's warning opinions are inadmissible and should be excluded.

II. The Court should limit Dr. Elliott's opinions about certain future conditions.

Under Kentucky law, a plaintiff must introduce evidence to show that it is *probable* that the conduct of the defendant was a cause in fact of the result. *Stevens v. Keller Ladders*, 1 F. App'x 452, 460 (6th Cir. 2001). A mere possibility of such causation is not enough. *Id.* The Court should preclude Dr. Elliott from testifying that Ms. Garvin's TVT-O device caused certain conditions that are not based on reliable methodology and that are not made within a reasonable degree of medical certainty.

Dr. Elliott vaguely predicts in his Case-Specific Report that "[w]ithout a major reduction in her symptoms [Ms. Garvin] is unlikely to ever regain the benefit of physical intimacy again in

her life.” Ex. A, Elliott Case-Specific Report at p. 45. Dr. Elliott also states in his report that “studies have shown the long-term negative impact leading to feelings of isolation, loneliness, depression and suicide.” Id. Dr. Elliott does not opine that Ms. Garvin will develop these mental conditions, and therefore, any such testimony should be disallowed. Similarly, Dr. Elliott can only speculate about the level of “reduction” of what he vaguely describes as “symptoms” will occur for Ms. Garvin in the future. The Court should preclude Dr. Elliott from testifying about potential future conditions that are based on mere possibilities and that he has not opined that Ms. Garvin will sustain within a reasonable degree of medical certainty. Any such opinions would be unreliable and prejudicial and should be excluded.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court limit Dr. Elliott’s opinions consistent with the above.

Respectfully Submitted,

/s/ William M. Gage

William M. Gage
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
William.gage@butlersnow.com

/s/ Susan M. Robison

Susan Robinson (W. Va. Bar #5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
srobinson@tcspllc.com

Counsel for Defendants Ethicon, Inc. and
Johnson & Johnson

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO <i>Jana Garvin, et al. v. Ethicon, Inc., et al.</i> <i>Case No. 2:12-cv-19899</i>	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I, William M. Gage, certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage

William M. Gage
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
William.gage@butlersnow.com